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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/285,060 04/02/99 CATT M PM250498

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QM12/0425

EXAMINER

MARMOR 11,C

ART UNIT

PAPER NUMBER

3736

DATE MAILED:

04/25/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/285,060

Applicant(s)
Catt et al.

Examiner
Charles Marmor, II

Group Art Unit
3736



☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-50 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-50 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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DETAILED ACTION

Specification

1. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

2. Claims 8,10,22,24,27, and 36 are objected to because of the following informalities:
Proper claim language protocol states that the word "means" in an apparatus claim limitation should be followed by "for [performing a specified function]." For example, in claim 8, line 2, "receiving means to receive" apparently should read --receiving means for receiving--.
Appropriate correction is requested.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 1-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 uses purely functional language to disclose the present invention. No structure is disclosed to perform the functions as claimed. Furthermore, there are no structural limitations disclosed which form the monitoring device.

Regarding claims 10 and 11, the word "means" is preceded by the word(s) "electronic data transmission" in an attempt to use a "means" clause to recite a claim element as a means for performing a specified function. However, since no function is specified by the word(s) preceding "means," it is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967).

Claims 17 and 18 provide for the use of a method for determining the time of maximum fertility in the mammalian ovulation cycle, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a method without any active, positive steps delimiting how this use is actually practiced. Claims 17-26 are further rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678

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(Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Regarding claim 22, the word "means" is preceded by the word(s) "computer" in an attempt to use a "means" clause to recite a claim element as a means for performing a specified function. However, since no function is specified by the word(s) preceding "means," it is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967).

Regarding claims 24-26, the word "means" is preceded by the word(s) "electronic data transmission" in an attempt to use a "means" clause to recite a claim element as a means for performing a specified function. However, since no function is specified by the word(s) preceding "means," it is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967).

Claim 27-50 are rejected under 35 U.S.C. 112, second paragraph, because it is unclear whether an essential method step has been omitted from the claimed method, such as "testing a patient..."; or if the claimed method solely involves providing a plurality of apparatuses, downloading data stored in one of the apparatus to a transmission medium; and then inputting the data from the transmission medium to a computer for data analysis.

Further regarding claim 27, the word "means" is preceded by the word(s) "electronic data transmission" or "computer" in an attempt to use a "means" clause to recite a claim element as a

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means for performing a specified function. However, since no function is specified by the word(s) preceding "means," it is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967).

Regarding claims 28,45,46, and 49, the word "means" is preceded by the word(s) "electronic data transmission" in an attempt to use a "means" clause to recite a claim element as a means for performing a specified function. However, since no function is specified by the word(s) preceding "means," it is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967).

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Catt et al. ('778). Catt et al. ('778). teach a method and apparatus for monitoring the status of a current ovulation cycle of an individual female subject. A body fluid, particularly urine, is tested for concentrations of a pair of analytes significant in relation to the status of the ovulation cycle. A detectable

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concentration of a first analyte, luteinising hormone, is indicative of maximum fertility or ovulation. A detectable concentration of a second analyte, estradiol or E3G, before the detection of the first analyte is indicative of an elevated chance of fertility or pre-ovulation. At least one testing device is used with a monitoring device in order to monitor the fertility status. The monitoring device includes receiving means for receiving a testing device, reading means for reading test signals from the testing device(s), electronic processing means for interpreting the test signals, interface means, electronic transmission means, and display means for providing indications of fertility.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 27-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Catt et al. ('778). in view of Beach et al. Catt et al. ('778) teach all of the limitations of the claims except that data is downloaded from a monitoring device to a data transmission means and then input into a computer for analysis by a professional. It is well known in the art of monitoring devices

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that data can be downloaded from a monitoring device to a transmission means and input into a remote computer for further analysis. Beach et al. teach a portable fertility monitor which enables data to be downloaded onto a data transmission means to be input into a computer for further data analysis by a professional. It would have been obvious to one skilled in the art at the time the invention was made to provide a fertility monitor similar to that taught by Catt et al. ('778) with the ability to download data to a computer at a remote location in view of the teachings of Beach et al. so that the data can be analyzed by a fertility specialist in a professional environment.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Regas et al. teach a method and apparatus for predicting and detecting the onset of ovulation. Coley et al. teach a method for monitoring ovulation involving measurement of at least one urinary component of significance in the cycle. Klemm et al. teach a method for monitoring mammalian reproductive cycles by monitoring variations in the quantity of one or more volatile compounds present in a body constituent sample. Cutler et al. teach a method of determining the onset of the fertile period of a human female by monitoring concentrations of axillary androstenediol and dehydroepiandrosterone. Marett teaches a method and apparatus for predicting the fertility status of a human female using analysis of a body fluid.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles Marmor, II whose telephone number is (703)305-3521. The examiner can normally be reached Monday - Thursday from 7:30am - 5:00pm. Additionally, the SPE for Art Unit 3736 is Cary O'Connor whose phone number is (703)308-2701, and the group's central fax number is (703)305-3590.

Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist whose telephone number is (703)308-0858. The fax number for Art Unit 3736 is (703)308-0758.


CARY O'CONNOR
SUPERVISORY PATENT EXAMINER
GROUP 3700


CAM

April 21, 2000